SMARTCRT™
Technology

Boston Scientific
Advancing science for life™

The SMART-MSP Clinical Trial
Strategic Management to Improve CRT Using Multi-Site Pacing

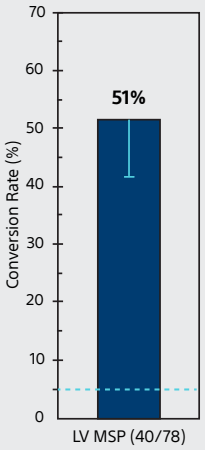
Study Objective
The SMART-MSP Trial was designed to demonstrate the safety and effectiveness of the MultiSite pacing (MSP) feature in the Boston Scientific RESONATE™ family of CRT devices in heart failure patients that do not respond to conventional CRT.

Study Design
The SMART-MSP Trial was a prospective, single-arm, multi-center, post-approval study conducted with 584 patients in the United States.

Primary Endpoints[1]

Effectiveness
MSP in the SMART-MSP Trial was associated with improved clinical response in subjects who were non-responders to conventional CRT. At 6 months, 74% of patients responded to CRT based on Clinical Composite Score. After an additional 6 months with MSP enabled, **51% of the remaining non-responders converted to responders.**

MSP Effectiveness

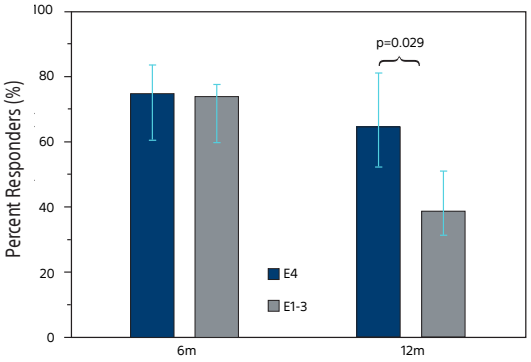


Safety
The MSP feature-related complication-free rate at 180 days post MSP on is 99%, exceeding the performance goal of 90%.

Additional Findings[1]

ACUITY™ X4 Lead
MSP with the E4 proximal pacing electrode in the ACUITY X4 LV lead is associated with a **higher response rate (64.5% vs. 38.6%)** in patients that were non-responders at 6 months.

LV Electrodes and CCS Response



Responders at 6 and 12 months by electrode usage

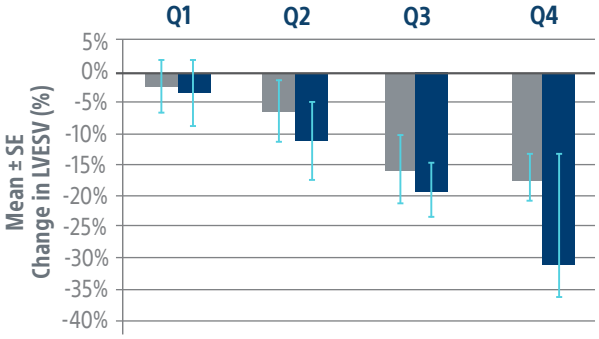
Battery Life
Programmer estimate of remaining battery life*:
- Pre-MSP @ 6m 8.9 ± 2.1 years
- Post-MSP @ 12m 8.1 ± 2.2 years

*Data are Mean ± SD

SMART-MSP exceeded both its primary safety and effectiveness endpoints. The trial demonstrated the Boston Scientific MultiSite Pacing feature was effective in converting non-responders to responders **with minimal impact to battery life.**

SmartCRT™ technology provides solutions to improve CRT-D response rate beyond industry standard of 70%.

Patients with long RV-LV and SmartDelay™ feature achieved an **~80% response rate** in the SMART-AV trial, highlighting the value of using the SmartDelay feature in conjunction with VectorGuide™ software.[2]



	Q1: ≤ 40 ms	Q2: 45 – 65 ms	Q3: 70 – 100 ms	Q4: ≥ 105 ms
Fixed (Mean Change)	-2%	-6%	-16%	-17%
SmartDelay (Mean Change)	-3%	-11%	-19	-31%
Fixed (% Responders)	36%	45%	56%	48%
SmartDelay (% Responders)	33%	47%	63%	**80%**

- In the SMART-MSP trial, **51% of non-responders at 6 months converted to responders** at 12 months with MultiSite Pacing turned ON
- Boston Scientific SmartCRT technology, including ACUITY X4 leads, VectorGuide software, SmartDelay feature, and MultiSite Pacing can contribute to an **over 90% response rate**

1. Saba S, Nair D, Ellis CR, et al. Strategic Management to Improve CRT Using Multi-Site Pacing (SMART-MSP) Investigators. Usefulness of Multisite Ventricular Pacing in Nonresponders to Cardiac Resynchronization Therapy. *Am J Cardiol*. 2022 Feb 1;164:86-92. doi: 10.1016/j.amjcard.2021.10.027. Epub 2021 Nov 20. PMID: 34815062.

2. Gold MR, et al. Effect of Interventricular Electrical Delay on Atrioventricular Optimization for Cardiac Resynchronization Therapy. *Circ Arrhythm Electrophysiol*. 2018 Aug;11(8):e006055.

CRT-D Systems — RESONATE™ HF, RESONATE™, RESONATE™ X4, VIGILANT™, VIGILANT™ X4, MOMENTUM™, MOMENTUM™ X4

Indications and Usage: These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

Contraindications: There are no contraindications for this device.

Warnings: Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4-LLHH or DF4-LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, and MOMENTUM devices except for those with an RA: IS-1; RV: IS-1/DF-1; LV: LV-1 lead connection are considered MR Conditional. VIGILANT devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

Precautions: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, follow up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events: Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Rx only. 92436222 (Rev. A)

ACUITY X4™

INDICATIONS: This Boston Scientific lead is indicated for use as follows: Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4 lead is a steroid-eluting (dexamethasone acetate) IS4 quadripolar lead.

CONTRAINDICATIONS: Use of this Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate.

WARNINGS: Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. When using a right ventricular (RV) pace/sense lead in conjunction with this left coronary venous pace/sense lead, it is recommended that a polyurethane- insulated lead be used. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats and clamps. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLHH/LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Implant of the system cannot be performed in an MRI site zone III (and higher). Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

PRECAUTIONS: Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing. Failure to observe these cautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

POTENTIAL ADVERSE EVENTS: Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Acceleration of arrhythmias; Adverse reaction to procedure (e.g., bradycardia, general, respiratory, hypotension); Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Shunting current or insulating myocardium during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide

Additionally, potential adverse events associated with implantation of a coronary venous lead system include: Allergic reaction to contrast media; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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